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Dorit Plat

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EXAMINER

FISHER, ABIGAIL L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,782	Applicant(s) PLAT ET AL.	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 24, 25, 27, 28, 30-40 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) 36-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24, 25, 27, 28, 30-35 and 42-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/12/07, 6/23/08, 8/19/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Response to Election/Restriction filed on January 5 2009 is acknowledged. Claims 23, 26, 29 and 41 were/stand cancelled. Claims 1-22, 24-25, 27-28, 30-40 and 42-44 are pending.

Priority

It is noted that this application appears to claim subject matter disclosed in PCT/IL04/00895 filed September 26 2004. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen

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months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference

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in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Since there is no application data sheet, the applicant should insert the claim that this application is a 371 of PCT/IL04/00895 in the first sentence of the specification.

Information Disclosure Statement

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

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The information disclosure statements (IDS) submitted on 10/12/07, 6/23/08 and 8/19/08 were considered by the examiner.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on January 5 2009 is acknowledged. The traversal is on the ground(s) that the claims are drawn to a stable phosphatidylserine composition of matter, which is the special technical feature, and the art cited by the examiner as to show the special technical feature was known and therefore unity is lacking does not teach these stable composition of matter. This is not found persuasive because the instant claims and the prior art (Buchholz et al.) cited by the examiner are not patentably distinct as the both are compositions comprising phosphatidylserine. Applicants have argued that their recitation of stable in the preamble patentably distinguishes their invention over that of Buchholz et al. However, this is not persuasive as both compositions are directed to phosphatidylserine containing compositions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-22, 24-25, 27-28, 30-40 and 42-44 are pending in the application. Claims 36-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 5 2009. Accordingly, claims 1-22, 24-25, 27-28, 30-35 and 42-44 are being examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The specification by way of the prior art, while being enabling for enhancement of cognitive performance and learning ability and treating dementia, does not reasonably provide enablement for preventing memory loss. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by “undue experimentation,” the Federal Circuit has stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).¹

The factors that may be considered in determining whether a disclosure would

¹ As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is “undue”, not “experimentation”.

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require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Formal, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, relative skill level, and breadth of the claims

The instant invention is directed to phosphatidylserine compositions of matter that are utilized in preventing memory loss.

The relative skill of those in the art is high, that of an MD or PHD.

The state and predictability of the art

The state of the art (Kiliaan (WO 01/84961)) recognizes that phosphatidylserine and phosphatidylethanolamine are known to be utilized in the treatment of dementia such as Alzheimer's, which is one form of memory loss.

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The state of the art (Merck Manual, <http://www.merck.com/mmhe/sec06/ch083/ch083c.html?qt=memory%20loss&alt=sh>, 2008) recognizes that dementia whose symptoms include memory loss, problems using language, disorientation, disruptive or inappropriate behavior, etc. (symptoms section) can be caused by several disorders. These include Parkinson's disease, brain damage due to a head injury or certain tumors, Huntington's disease; Radiation therapy to the head, etc. (causes section). It is taught that for most dementias, no treatment can restore mental function. However, treating disorders that are worsening the dementia sometimes slows mental decline (treatment section). Furthermore, in terms of diagnosis it is taught that forgetfulness is usually the first sign noticed by family members or doctors (diagnosis section). It is taught that for certain disorders which result in dementia such as Alzheimer's disease, the cause of the disease is unknown (Alzheimer's section).

The lack of significant guidance from the specification or the prior art with regard to preventing memory loss utilizing the phosphatidylserine composition of matter makes practicing the scope of the invention unpredictable.

The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for preventing memory loss. One of ordinary skill would undergo undue experimentation in deducing if the compositions can be utilized to prevent memory loss and then determine what sort of administration regimen can actually be utilized to prevent memory loss. This is

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particularly difficult in light of the state of the art's recognition which indicates that causes of dementia include head injury which is difficult to predict when that would occur. Furthermore in light of the state of the art's recognition that age-related memory loss is diagnosed usually after signs of memory loss begin to appear and then treatment can only be utilized to suppress the decline of memory loss and not actually return memory function.

The working examples of the specification are directed towards formulating the compositions of the instant invention. However, the examples do not enable one to utilize the compositions to prevent memory loss.

The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used to prevent memory loss as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention as claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

The examiner would like to note that while intended uses are not given patentable weight, the enablement of compositions reciting activity or intended use must be considered. *In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991) and *In re Gardner*, 427 F. 2d 786, 166, USPQ 138 (C.C.P.A. 1970).

Claims 2, 9-22, 24-25, 27-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as lecithin, phospholipid, vitamin, anti-oxidant, mineral, sterol, amino acid, poly-unsaturated fatty acids and carbohydrate which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim(s) 2, 9-22, 24-25, 27-28, is(are) directed to encompass functional ingredient, bio-functional ingredient, nutritional proteins or peptides, sterol derivatives, carbohydrate derivatives, plant extracts, fermentation products, glyceride derivatives, and active ingredient, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these derivatives, functional ingredients, bio-functional ingredients, proteins, peptides, extracts, fermentation products and active ingredients meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The instant specification provides no guidance as to what proteins, peptides, functional ingredients, fermentation products and active ingredients are contemplated as falling within the scope of the instant claims. The MPEP indicates that the written description requirement for a claimed genus may be satisfied through sufficient description of a

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representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus. The specification provides insufficient written description to support the genus encompassed by the claim. **Note: MPEP 2163.**

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, functional ingredients, bio-functional ingredients, proteins, peptides, extracts, fermentation products and active ingredients, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, (Fed. Cir. 1991). In Fiddes v. Baird, 30 USPQ2d 1481, 1483, (Bd. Pat. App. & Int. 1993), claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can

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clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 6-17, 21-22, 24-25, 27-28, 30-35 and 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claims 3, 11, 22, 25 and 28 recite the broad recitation storage period of at least 6 months, and the claim also recites preferably at least 12 months and more preferably at least 24 months, which is the narrower statement of the range/limitation.

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Claim 4 recites the broad recitation phospholipase activity, and the claim also recites particularly phospholipase D activity, which is the narrower statement of the range/limitation.

Claim 6 recites the broad recitation salt, and the claim also recites preferably the sodium salt, which is the narrower statement of the range/limitation.

Claim 7 recites the broad recitation metal chelator, and the claim also recites preferably EDTA, which is the narrower statement of the range/limitation.

Claim 8 recites the broad recitation salt, and the claim also recites preferably the calcium salt, which is the narrower statement of the range/limitation.

Claim 9 recites the broad recitation form of a oil, and the claim also recites preferably a medium-chain triglyceride, which is the narrower statement of the range/limitation.

Claim 10 recites the broad recitation about 1 to about 90% (w/w) phosphatidylserine, and the claim also recites preferably from about 2.5 to about 55 (w/w)%, which is the narrower statement of the range/limitation.

Claims 12 and 16 recites the broad recitation biofunctional ingredient, and the claim also recites preferably at least one of lecithin, phospholipids..., which is the narrower statement of the range/limitation.

Claim 13 recites the broad recitation a liquid base, and the claim also recites preferably a lipid base and more preferably an oil base, which is the narrower statement of the range/limitation.

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Claim 14 recites the broad recitation from about 1 to about 70% (w/w), and the claim also recites preferably about 5 to 45% (w/w), which is the narrower statement of the range/limitation.

Claim 15 recites the broad recitation triglyceride base, and the claim also recites particularly medium-chain triglyceride base or vegetable oil, which is the narrower statement of the range/limitation.

Claims 33 and 34 recite the broad recitation memory loss, and the claim also recites particularly age-related memory loss, which is the narrower statement of the range/limitation.

Claims 2, 9, 13, 21, 24 and 27 as currently written are vague and indefinite. The claim recites the composition of matter preferably comprises from about 1 to about 99% (w/w) phosphatidylethanolamine. The presence of the word preferably results in the claim being indefinite because it is unclear if the phosphatidylethanolamine is required by the claims or only an optional component.

Claims 2, 9, 13, 21, 24 and 27 as currently written are vague and indefinite. The claim recites omega-3 source and omega-6 source. However, neither the instant claim nor the instant specification indicates what this source is or what Omega-3 or Omega-6 is referring to. Is it particular fatty acids or particular lipids? Furthermore it is unclear if only the source has to be present in an amount from about 1 to about 99% or if the Omega-3 or Omega-6 chemical needs to be present in this amount.

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Claims 2, 9, 13, 21, 24 and 27 as currently written are vague and indefinite. The claims recite the composition of matter comprises other functional ingredients. Neither the instant claims nor the instant specification indicates what is meant by the term "other functional ingredients" or what types of ingredients would be considered "other functional ingredients". The resulting claim does not clearly set forth the metes and bounds of the patent protection desired for other functional ingredients.

The term "substantially soluble" in claim 6 is a relative term which renders the claim indefinite. The term "substantially soluble" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "substantially non-soluble" in claim 8 is a relative term which renders the claim indefinite. The term "substantially soluble" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 12 and 16 as currently written are vague and indefinite. The claims recite nutritional carbohydrates. However, neither the instant claims nor the instant specification indicates what these nutritional carbohydrates are. Furthermore, no guidance is given as to differentiate nutritional carbohydrates over other types of carbohydrates. The resulting claim does not clearly set forth the metes and bounds of the patent protection desired for nutritional carbohydrates.

Claims 9 and 13 as currently written are vague and indefinite. Claim 13 recites a dispersion of phosphatidyl serine. However, the phosphatidylserine appears to be the same as that claimed in claim 9 in which the phosphatidylserine is dissolved in oil. Claim 13 recites dispersing the same phosphatidylserine in the same oil as the phosphatidylserine is dissolved. Therefore, it is unclear how the same phosphatidylserine can both be dispersed and dissolved. It is noted that claim 13 does not recite that the phosphatidylserine is a salt thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The instant application claims a composition of matter comprising from about 1 to about 99% (w/w) phosphatidylserine.

Claims 1, 3-8, 18 and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchholz et al. (US Patent No. 6514973, cited on PTO Form 1449).

Buchholz et al. exemplify a composition consisting of phosphatidylserine, Choline, S-adenosylmethionine, serine, and L-5-methyltetrahydrofolic acid. The amount of phosphatidylserine is 9% based on the total weight of the composition. It is taught that component A is phosphatidylserine and their physiologically acceptable salts

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(column 4, lines 37-40). Physiologically acceptable salts include sodium, potassium, magnesium, calcium, ammonium and substituted ammonium salts (column 5, lines 17-24).

While Buchholz et al. do not exemplify the salt form of the phosphatidylserine. Therefore are only two choices for the phosphatidylserine, the free base or the salt form. Therefore, one of ordinary skill in the art can immediately envision utilizing the salt form of the phosphatidylserine.

Regarding claim 7, the use of a metal chelator to form the sodium salt is a product by process. **Note MPEP 2113 [R-1]** “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The MPEP also indicates that “the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). Since the claim is directed to a sodium salt of phosphatidylserine and Buchholz et al. teach the sodium salt, the resulting product is the same.

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Regarding the preamble of the claim reciting the term stable, the recitation stable has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The claim recites only one component which is phosphatidylserine, which is found in the product of Buchholz et al.

Regarding the functional limitation of claims 4 and 42-44, Buchholz et al. is silent as to the phospholipase activity. However, the composition comprises the same phosphatidylserine. It is noted that *In re Best* (195 USPQ 430, C.C.P.A. 1997) and *In re Fitzgerald* (205 USPQ 594, C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Regarding claim 18, for use as a dietary supplement is a recitation of an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of

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performing the intended use, then it meets the claim. Buchholz et al. teach the composition is a tablet. Therefore, the prior art is capable of being able to perform the intended use.

Claims 1, 3-5, 18 and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (WO 01/84961).

Kiliaan et al. exemplify preparations comprising phospholipids. Example 1 is a capsule comprising about 14% phosphatidylserine. Example 2 is a pudding comprising about 1% phosphatidylserine. Example 3 is a powdered concentration comprising about 1% phosphatidylserine.

Regarding the preamble of the claim reciting the term stable, the recitation stable has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The claim recites only one component which is phosphatidylserine, which is found in the product of Kiliaan et al.

Regarding the functional limitation of claims 4 and 42-44, Kiliaan et al. is silent as to the phospholipase activity. However, the composition comprises the same phosphatidylserine. It is noted that *In re Best* (195 USPQ 430, C.C.P.A. 1997) and *In re*

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Fitzgerald (205 USPQ 594, C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Regarding claim 18, for use as a dietary supplement, nutraceutical food and/or drug additive is a recitation of an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Killian et al. teach the composition is a capsule. Therefore, the prior art is capable of being able to perform the intended use.

Claims 1, 3-5, 18 and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Hensley et al. (WO 01/82902).

Hensley et al. exemplify preparations comprising mixed membrane phospholipids. Example 1 a composition comprising one or more phospholipids selected from the group consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine and phosphatidylinositol. The exemplified amounts of the phospholipids is from 87-96%.

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Regarding the preamble of the claim reciting the term stable, the recitation stable has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The claim recites only one component which is phosphatidylserine, which is found in the product of Hensley et al.

Regarding the functional limitation of claims 4 and 42-44, Kiliaan et al. is silent as to the phospholipase activity. However, the composition comprises the same phosphatidylserine. It is noted that *In re Best* (195 USPQ 430, C.C.P.A. 1997) and *In re Fitzgerald* (205 USPQ 594, C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Regarding claim 18, for use as a dietary supplement, nutraceutical food and/or drug additive is a recitation of an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior

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art. If the prior art structure is capable of performing the intended use, then it meets the claim. Hensley et al. teach the composition is for nasal administration. Therefore, the prior is capable of being able to perform the intended use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 21-22, 24-25, 27-28, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. in view of Haynes et al. (US Patent No. 5015483).

Applicant Claims

The instant application claims a composition comprising from about 1 to about 99% (w/w) phosphatidylserine, from about 1 to about 99% (w/w) other functional ingredients, from about 1 to about 99% (w/w) phosphatidylcholine, from about 1 to about 99% (w/w) phosphatidylethanolamine, from about 1 to about 99% (w/w) phosphatidylinositol, from about 1 to about 99% (w/w) Omega-3 source, from about 1 to about 99% (w/w) Omega-6 source and/or from about 1 to about 99% (w/w) sterol or sterol esters.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Kiliaan et al. is directed to preparations for the prevention and/or treatment of vascular disorders. It is taught that it is known in the art that phosphatidylserine can be utilized for improving cerebration, in particular for the treatment of Parkinson's disease and dementia such as Alzheimer's disease. Additionally it is known that compounds such as phosphoethanolamine are utilized for the treatment of Alzheimer's disease (page 5, lines 8-14). The invention of Kiliaan et al. comprises long chain polyunsaturated fatty acids, phospholipids which fraction contains at least two different

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phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and compounds which factor in methionine metabolism such as folic acid, vitamin B12, vitamin B6, magnesium, zinc (page 5, lines 23-31). The long chain fatty polyunsaturated fatty acids are preferably omega-3 and/or omega-6 fatty acids (column 6, lines 12-13). It was found that a mixture of omega-3 and omega-6 long chain polyunsaturated fatty acids should be included in a ratio of omega 3 to omega 6 of about 2.5 to 5.5 w/w. Exemplified formulations comprise phospholipids from egg which comprise DHA (an omega-3) and AA (an omega-6), phosphatidylcholine and phosphatidylethanolamine. The amount of phospholipids added from egg is 4 g which provides about 20 mg of DHA and 20 mg of AA and about 77% phosphatidylcholine and about 16% phosphatidylethanolamine. Also added to this compound is phosphatidylserine in 100 mg, encapsulated fish oil in 0.3 g which provides about 30 mg of DHA and 30 mg EPA (an omega-3) and single cell oil which provides 25 mg of AA. This example (example 2) additionally comprises other vitamins and minerals. Other exemplified forms are a powder and a capsule.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

While Kiliaan et al. teach that the phospholipid fraction contains at least two different phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and exemplifies formulations comprising three different phospholipids. Kiliaan et al. do not exemplify formulations comprising all four phospholipids.

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Kiliaan et al. do not teach incorporating sterol or sterol esters. However, this deficiency is cured by Haynes et al.

Haynes et al. teach liposome compositions for the stabilization of oxidizable substances. The compositions comprise phospholipids and omega-3 and omega-6 fatty acids (column 5, lines 39-41). It is taught that cholesterol is known to be a stabilizer of phospholipids (column 2, lines 51-55). It is taught that in compositions comprising phospholipids other lipids such as sterols and cholesterol can be added in order to reduce the permeability, strengthen the vesicle wall and generally improve the physical characteristics of a resulting liposome (column 10, lines 5-11). The amount utilized will vary but generally not exceed a 1:1 ratio with the selected phospholipid (column 10, lines 15-17).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Kiliaan et al. and Haynes et al. and utilize phosphatidylserine, phosphatidylcholine, phosphatidylethanolamine, and phosphatidylinositol. One of ordinary skill in the art would have been motivated to utilize all four phospholipids as Kiliaan et al. teach utilizing two or more of these four phospholipids and exemplify formulations comprising three of the four phospholipids. It would have been obvious to one of ordinary skill in the art to utilize all four phospholipids as they are all taught as being suitable, mixtures are taught as suitable, mixtures of three or more are exemplified and they are all taught as being utilized for the same purpose. Particularly exemplified are a combination of phosphatidylcholine,

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phosphatidylethanolamine, phosphatidylinositol for the improvement of vasoendothelial function. It would have been obvious to one of ordinary skill in the art to add phosphatidylserine as it is taught for being useful for treating dementia. Therefore, it would have been obvious to one of ordinary skill in the art to add phosphatidylserine for the added benefit of treatment dementia as taught by Kiliaan et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Kiliaan et al. and Haynes et al. and utilize sterol in the composition. One of ordinary skill in the art would have been motivated to add a sterol in order to improve the stability of the lipids as taught by Haynes et al.

Regarding the claimed amounts, it is taught that the daily intake should be at least 200 mg of phospholipids, 120 mg long chain polyunsaturated fatty acids, at least 200 micrograms of folic acid and at least 0.5 g of citrate (page 11, lines 8-14). This equates to a phospholipid amount of about 24% and a long chain polyunsaturated amount of about 15%. It is taught that for best results the ratio of phosphatidylcholine and/or phosphatidylethanolamine to phosphatidylserine and/or phosphatidylinositol is 0.5 to 20 (w/w) (page 7, lines 18-20). The ratio of omega-3 to omega-6 is about 2.5 to 5.5 (w/w). Haynes et al. teach that the amount of sterol will generally not exceed a 1:1 ratio with the phospholipid. Therefore, based on these general teachings of suitable amounts and ratios, it would have been obvious to one of ordinary skill in the art to manipulate the amounts of the phospholipids and the fatty acids in order to determine the optimal amount to include the formulations. "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to

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determine where in a disclosed set of percentage ranges is the optimum combination of percentages.” *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Regarding the claimed storage stability, Kiliaan et al. is silent. Haynes et al. do teach that incorporation of lipid stabilizers such as sterols can improve storage stability. Therefore, based on that teaching and that the compositions of Kiliaan et al. teachings comprising the same claimed ingredients, there is a reasonable expectation that the storage stability would be the same as instantly claimed. Because the PTO has no means to conduct analytical experiments and based on the substantially similar product components, the burden of proof is shifted to the Applicant to show that the functional limitation is not possessed by the prior art.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 2, 9-12, 19, 24-25, 30-31 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hensley et al. in view of Haynes et al. (US Patent No. 5015483).

Applicant Claims

The instant application claims a composition comprising from about 1 to about 99% (w/w) phosphatidylserine, from about 1 to about 99% (w/w) other functional ingredients, from about 1 to about 99% (w/w) phosphatidylcholine, from about 1 to

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about 99% (w/w) phosphatidylethanolamine, from about 1 to about 99% (w/w) phosphatidylinositol, from about 1 to about 99% (w/w) Omega-3 source, from about 1 to about 99% (w/w) Omega-6 source and/or from about 1 to about 99% (w/w) sterol or sterol esters.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

Hensley et al. is directed to composition for the rapid delivery of bioactive compounds. Exemplified formulations comprise mixed membrane phospholipids, omega-6 oils, and glycerin. It is taught that the phosphomatrix is prepared by combining one or more phospholipids selected from the groups consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, and phosphatidylinositol (examples). Amounts of the phospholipids exemplified are from 87-96%. It is taught that the forms of the composition can be that of an aerosol, a liquid or gel. The composition includes components such as fatty acids, oils or water (page 5, lines 21-31). Suitable oils include polyunsaturated oils and monounsaturated oils such as omega 3, omega 6 and DHA (column 2, lines 32-33).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

While Hensley et al. teach that the phosphomatrix comprises one or more phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine. Hensley et al. do not exemplify formulations comprising all four phospholipids. While Hensley et al.

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teach that omega-3 and omega-6 oils can be utilized, Hensley et al. do not exemplify formulations comprising both.

Hensley et al. do not teach incorporating sterol or sterol esters. However, this deficiency is cured by Haynes et al.

Haynes et al. teach liposome compositions for the stabilization of oxidizable substances. The compositions comprise phospholipids and omega-3 and omega-6 fatty acids (column 5, lines 39-41). It is taught that cholesterol is known to be a stabilizer of phospholipids (column 2, lines 51-55). It is taught that in compositions comprising phospholipids other lipids such as sterols and cholesterol can be added in order to reduce the permeability, strengthen the vesicle wall and generally improve the physical characteristics of a resulting liposome (column 10, lines 5-11). The amount utilized will vary but generally not exceed a 1:1 ratio with the selected phospholipid (column 10, lines 15-17).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Hensley et al. and Haynes et al. and utilize phosphatidylserine, phosphatidylcholine, phosphatidylethanolamine, and phosphatidylinositol. One of ordinary skill in the art would have been motivated to utilize all four phospholipids as Hensley et al. teach utilizing one or more of these four phospholipids. Since there are only four different phospholipids to choose from, which represents a finite number of different phospholipids, it would have been obvious to one of ordinary skill in the art to utilize a combination of all four as they are all taught as

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being suitable for the same purpose. Since they are all taught as being suitable for the same purpose, there is a reasonable expectation of success in utilizing combinations of the respective phospholipids.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Henley et al. and Haynes et al. and utilize both omega-3 and omega-6 fatty acids. One of ordinary skill in the art would have been motivated to utilize both as Hensley et al. teach that the matrix can comprise fatty acids and only teach two different fatty acids to incorporate. Therefore, it would have been obvious to one of ordinary skill in the art to utilize one or both of the fatty acids into the matrix.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Henley et al. and Haynes et al. and utilize sterol in the composition. One of ordinary skill in the art would have been motivated to add a sterol in order to improve the stability of the lipids as taught by Haynes et al.

Regarding the claimed amounts, it is taught that amounts of the phospholipids range from 87-96% and exemplified amounts of the fatty acid is 10 wt. %. Haynes et al. teach that the amount of sterol will generally not exceed a 1:1 ratio with the phospholipid. Therefore, based on these general teachings of suitable amounts and ratios, it would have been obvious to one of ordinary skill in the art to manipulate the amounts of the phospholipids and the fatty acids in order to determine the optimal amount to include the formulations. "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine

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where in a disclosed set of percentage ranges is the optimum combination of percentages.” *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Regarding the claimed storage stability, Hensley et al. is silent. Haynes et al. does teach that incorporation of lipid stabilizers such as sterols can improve storage stability. Therefore, based on that teaching and that the compositions of Hensley et al. teachings comprising the same claimed ingredients, there is a reasonable expectation that the storage stability would be the same as instantly claimed. Because the PTO has no means to conduct analytical experiments and based on the substantially similar product components, the burden of proof is shifted to the Applicant to show that the functional limitation is not possessed by the prior art.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 2, 9-19, 21-22, 24-25, 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes et al.

Applicant Claims

The instant application claims a composition comprising from about 1 to about 99% (w/w) phosphatidylserine, from about 1 to about 99% (w/w) other functional ingredients, from about 1 to about 99% (w/w) phosphatidylcholine, from about 1 to about 99% (w/w) phosphatidylethanolamine, from about 1 to about 99% (w/w)

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phosphatidylinositol, from about 1 to about 99% (w/w) Omega-3 source, from about 1 to about 99% (w/w) Omega-6 source and/or from about 1 to about 99% (w/w) sterol or sterol esters.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

Haynes et al. is directed to liposome compositions for the stabilization of oxidizable substances. Liposomes are prepared from a wide variety of lipid compounds including phospholipids. Phospholipids taught and exemplified include phosphatidylserine, phosphatidylinositol, phosphatidylcholine, phosphatidylethanolamine, cholesterol, etc. and mixtures thereof (claim 6 and column 7, lines 24-35). Fish oils and in particular omega-6 and omega-3 fatty acid fish oils are known to be beneficial in controlling the cholesterol level in blood and in preventing thrombotic disturbances (column 5, lines 39-56). The invention is directed to a method of effectively stabilizing readily oxidizable lipids. The liposomes prepared provide more stable lipids (column 6, lines 67-68). It is taught that the liposomes which can be readily dispersed in an aqueous medium or in a lipid medium (column 7, lines 6-7). It is taught that liposomes can be added directly to food preparations containing a high fat content such as margarines (column 7, lines 40-42). It is taught that the liposomes have the distinct advantage of being quite stable and an effective stabilizing means for reactive and oxidizable lipophilic materials (column 9, lines 22-24). It is taught that cholesterol is known to be a stabilizer of phospholipids (column 2, lines 51-55). It is taught that in compositions comprising phospholipids other lipids such as sterols and cholesterol can be added in order to reduce the permeability, strengthen the vesicle wall and generally improve the physical characteristics of a

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resulting liposome (column 10, lines 5-11). The amount utilized will vary but generally not exceed a 1:1 ratio with the selected phospholipid (column 10, lines 15-17). It is taught that the liposome may be solid at room temperature and fluid when consumed to increase the rate of release of the lipophilic component to provide proper taste and mouth feel (column 10, lines 58-62). It is taught that the margarine will typically comprise 70 to 80% hydrogenated and interesterified vegetable oil (column 12, lines 67-68). The amount of fish oil content is between 3 and 5% (column 13, lines 5-9). Cholesterol is claimed in an amount of about 3 to 5% (claim 7). Exemplified amounts of phospholipid is 25% (example 1). It is taught that the liposomes can comprise additional additives such as vitamins, glycerol, preservatives, flavorants, antioxidants, etc. (column 11, lines 25-30).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

While Haynes et al. teach that the phospholipids utilized to form the liposome include phosphatidylserine, phosphatidylcholine, phosphatidylethanolamine, and phosphatidylinositol, Haynes et al. do not exemplify a formulation comprising all four phospholipids. While Haynes et al. teach that the encapsulated material includes fish oil, which comprises omega-6 and omega-3 fatty acids, Haynes et al. do not exemplify a formulation wherein the liposome which is comprises of the four different phospholipids encapsulates this source of fatty acid. While Haynes et al. teach one embodiment includes dispersing the liposome in margarine, which comprises vegetable, Haynes et al. do not exemplify a liposome comprising the four phospholipids in margarine. While

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Haynes et al. teach the incorporation of sterols for increased stability, Haynes et al. do not exemplify a liposome comprising the four phospholipids with a sterol.

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize all four phospholipids in the formation of the liposomes. One of ordinary skill in the art would have been motivated to utilize these phospholipids as Haynes et al. exemplify a formulation comprising one of the phospholipids and teach that the polar lipid bilayer can comprise at least one substance selected from a group which comprises the four phospholipids and mixtures of these phospholipids. Since all of the phospholipids are taught are being utilized for the same purpose and are all taught as suitable, one of ordinary skill in the art would have a reasonable expectation of success in utilizing all four in the formation of a liposome to encapsulate fish oil.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize sterol in the composition. One of ordinary skill in the art would have been motivated to add a sterol in order to improve the stability of the lipids as taught by Haynes et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to encapsulate fish oil which comprises both omega-3 and omega-6 fatty acids. One of ordinary skill in the art would have been motivated to encapsulate fish oil as it is taught and exemplified by Haynes et al. as a material to be encapsulated in order to improve its stability and mask the taste.

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It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilizing additional ingredients such as vitamins and antioxidants in the liposomes. One of ordinary skill in the art would have been motivated to add these ingredients as they are taught by Haynes et al. as being suitable to include and it would have been obvious to one of ordinary skill in the art to add customary additives to the liposome formulations.

Regarding the claimed amounts, exemplified amounts of the phospholipid is 25%, the taught amount of the fish oil is 1 to 10% and the taught amount of cholesterol is 3 to 5%. Therefore, based on these general teachings of suitable amounts and ratios, it would have been obvious to one of ordinary skill in the art to manipulate the amounts of the phospholipids and the fatty acids in order to determine the optimal amount to include the formulations. "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Regarding the claimed storage stability, Haynes et al. does teach that incorporation of lipid stabilizers such as sterols can improve storage stability and indicates that their compositions are shelf-stable. However, Haynes et al. is silent as the length of stability. Therefore, based on that teaching and that the compositions of Haynes et al. comprise the same claimed ingredients, there is a reasonable expectation that the storage stability would be the same as instantly claimed. Because the PTO has no means to conduct analytical experiments and based on the substantially similar

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product components, the burden of proof is shifted to the Applicant to show that the functional limitation is not possessed by the prior art.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 18 and 42-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

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claims 1-22 of copending Application No. 12/215080 (US 20090074857). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a composition of matter comprising from about 1 to about 99% (w/w) phosphatidylserine.

Copending '080 claims a preparation comprising a mixture of serine glycerophospholipic conjugates with EPA and DHA. The compounds claims are phosphatidyl serines. The amounts claimed are 10 to 50%.

Therefore both the instant application and copending '080 are directed to composition comprising phosphatidylserine.

Regarding the preamble of the claim reciting the term stable, the recitation stable has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The claim recites only one component which is phosphatidylserine, which is found in the product of Copending '080.

Regarding the functional limitation of claims 4 and 42-44, Copending '080 is silent as to the phospholipase activity. However, the composition comprises the same phosphatidylserine. It is noted that *In re Best* (195 USPQ 430, C.C.P.A. 1997) and *In re*

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Fitzgerald (205 USPQ 594, C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Regarding claim 18, for use as a dietary supplement is a recitation of an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Copending '080 claims the composition is a capsule, tablet, syrup or other dietary supplement delivery system. Therefore, copending '080 is capable of being able to perform the intended use.

Therefore, the scopes of the copending claims and the instant application overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-5, 18 and 42-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-36 of copending Application No. 11872258 (US 20080085319) and 26-37 of copending Application No. 11/872440 (US 20080085320). Although the

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conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant claims are set forth above.

Copending '258 claims a method of treating a subject suffering from a disorder comprising a mixture of serine glycerophospholipid conjugates with EPA and DHA with amount of EPA and DHS being from 20 to 50%.

Copending '440 claims a method of treating a subject suffering from a cognitive or mental condition or disorder which comprises administered a serine glycerophospholipid conjugate with EPA and DHA wherein the amount of EPA and DHA present is from 10 to 50%.

Both '258 and '440 indicate the preparation can be in the form of a pharmaceutical composition.

Therefore both the instant application and copending '258 and '440 are directed to composition comprising phosphatidylserine.

Regarding the preamble of the claim reciting the term stable, the recitation stable has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481

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(CCPA 1951). The claim recites only one component which is phosphatidylserine, which is found in the product of Copendings '258 and '440.

Regarding the functional limitation of claims 4 and 42-44, Copendings '258 and '440 are silent as to the phospholipase activity. However, the composition comprises the same phosphatidylserine. It is noted that *In re Best* (195 USPQ 430, C.C.P.A. 1997) and *In re Fitzgerald* (205 USPQ 594, C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Regarding claim 18, for use as a dietary supplement is a recitation of an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Copendings '258 and '440 claims preparation is a pharmaceutical composition. Therefore, copendings '258 and '440 are capable of being able to perform the intended use.

Therefore, the scopes of the copending claims and the instant application overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 1, 3-5, 18 and 42-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 57-63, 70-75 and 77-79 of copending Application No. 11912925 (US 20090011075). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant claims are set forth above.

Copending '925 claims a preparation comprising a mixture of glycerophospholipids being phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, and phosphatidylinositol wherein the phospholipids are included in an amount of at least 1%. Also claimed are dietary supplements comprising this composition.

Therefore both the instant application and copending '925 is directed to composition comprising phosphatidylserine.

Regarding the preamble of the claim reciting the term stable, the recitation stable has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The claim recites only one component which is phosphatidylserine, which is found in the product of copending '925.

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Regarding the functional limitation of claims 4 and 42-44, Copending '925 is silent as to the phospholipase activity. However, the composition comprises the same phosphatidylserine. It is noted that *In re Best* (195 USPQ 430, C.C.P.A. 1997) and *In re Fitzgerald* (205 USPQ 594, C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Regarding claim 18, for use as a dietary supplement is a recitation of an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Copending '925 claims a dietary supplement. Therefore, copending '925 is capable of being able to perform the intended use.

Therefore, the scopes of the copending claims and the instant application overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 1, 3-5, 18 and 42-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 57-63, 70-75 and 77-79 of copending Application No. 11912925 (US 20090011075). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant claims are set forth above.

Copending '925 claims a preparation comprising a mixture of glycerophospholipids being phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, and phosphatidylinositol wherein the phospholipids are included in an amount of at least 1%. Also claimed are dietary supplements comprising this composition.

Therefore both the instant application and copending '925 is directed to composition comprising phosphatidylserine.

Regarding the preamble of the claim reciting the term stable, the recitation stable has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The claim recites only one component which is phosphatidylserine, which is found in the product of copending '925.

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Regarding the functional limitation of claims 4 and 42-44, Copending '925 is silent as to the phospholipase activity. However, the composition comprises the same phosphatidylserine. It is noted that *In re Best* (195 USPQ 430, C.C.P.A. 1997) and *In re Fitzgerald* (205 USPQ 594, C.C.P.A. 1980) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Regarding claim 18, for use as a dietary supplement is a recitation of an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Copending '925 claims a dietary supplement. Therefore, copending '925 is capable of being able to perform the intended use.

Therefore, the scopes of the copending claims and the instant application overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616